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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,655	08/06/2002	Steven E Rokita	55859-024	5726

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,655	ROKITA ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 16-20, 22, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-15, 21, 23 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20020806</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1654

1. Claims 7-10, 16-20, 22, 24, and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 21, 2006.

Applicant's election with traverse of the invention of Group I, and the species compound A, in the reply filed on August 21, 2006 is acknowledged. The traversal is on the ground(s) that there is a single technical feature in common among the claimed inventions. This is not found persuasive because the prior art applied against the claims shows that the claims lack the same or corresponding special technical feature. Further, while Applicants allege that compounds A, B, and C share the common significant structural feature of a nickel reagent having a square planar four-coordinate system, the instant claims are also drawn to derivatives, which are not required to possess such a structural feature. Dependent claim 5, which specifies a square planar 4-coordinate system, is also evidence that this feature is not required of all the compounds embraced by the independent claim.

The requirement is still deemed proper and is therefore made FINAL.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. A paper in the Image File Wrapper dated October 25, 2005 indicates that STIC has approved a sequence listing comprising two nucleotide sequences. However, the paper copy of the Sequence Listing and the statements required by 37 CFR 1.825(a) and (b), which presumably were submitted with the computer readable form of the Sequence Listing, are missing from the image file wrapper. Applicants are required to re-submit the paper copy and statements so that the image file wrapper is complete.

3. The disclosure is objected to because of the following informalities: SEQ ID NOS must be inserted after the nucleotide sequences occurring at page 9, line 11, and page 10, line 3. SEQ ID NOS must also be inserted after the nucleotide sequences occurring in Figures 7 and 8, or

Art Unit: 1654

more preferably, in the Brief Description of these figures. See 37 CFR 1.821(d). Appropriate correction is required.

4. Claims 1-6, 11-15, 21, 23, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 states that the compound comprises a labeled nickel complex "and" derivatives of Structures I-II. The use of the conjunction "and" indicates that the complexes and the derivatives of Structures I-II are two distinct components of the compound. However, Structures I-II explicitly require complexed nickel, and thus it is unclear if the complexes and the structures are actually distinct components. For analogous reasons, claim 21 is also indefinite. In claim 1, the term "derivatives" at claim 1, line 1, is indefinite because it is not clear what kind of similarity, e.g., structural and/or functional, and what degree of similarity, is necessary between a compound and Applicant's Structures I-II in order for the compound to be considered a derivative of Structures I-II and therefore to be embraced within the scope of Applicants' claims. The term is not defined either in Applicants' disclosure or in the art. For analogous reasons, the term "derivatives" in claims 2 and 21 is also indefinite. At claim 1, page 4 of the amendment filed August 21, 2006, line 4, the variable G' is used, but is not defined in the claim. At claim 1, page 4, line 5, the phrase "simple amide" is indefinite because it is not clear what distinguishes a simple amide from a non-simple or complex amide. At claim 1, page 4, line 7, the requirement for a "stable structure" is indefinite because "stable" is not defined either in Applicants' disclosure or in the art. Stability is a relative term and is highly dependent upon the environment in which the compound is located, but Applicants have provided no guidelines or conditions with which to determine whether or not a particular compound is stable

Art Unit: 1654

or not. The meaning of the term “flag element” in claim 15 is not known. It is unclear what structure and/or function (other than being a label) a flag element must possess. The term is not defined in Applicants’ specification, in the U.S. patent databases, or in various reference books consulted by the examiner. Claim 26 is indefinite because the two formulas appear to be the same, apart from a change in orientation and the use of “Me” as an alternative to “CH₃”. Claim 26 is indefinite because it requires the complex to require a “labeled” nickel complex, but the formulas, which do indicate that complexed nickel is present, do not appear to comprise a label. The relationship among the complex, the compounds of the recited formulas, and label is unclear.

5. Claims 1-6, 11-15, 21, and 23 are objected to because of the following informalities: In claim 1, Structure II, the superscript for the R group is illegible. At claim 1, page 4, line 4, a semicolon should be inserted at the end of the line. Claims 2 and 21 do not end with periods. Appropriate correction is required.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 5, 6, 11-13, 21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Schally et al (U.S. Patent No. 5,258,492). Schally et al teach LHRH analogs, in which the second amino acid residue (counting from the N-terminus) is histidine, conjugated to nickel complexes. The complexes comprise salicylamine groups, cationic groups, and detectable labels. See, e.g., column 4, lines 3-4; column 8, lines 42-45, 48-49, and 61-63; and column 27,

Art Unit: 1654

lines 64-68. The LHRH analogs of Schally et al correspond to Applicant's detectable protein ligands/labels. The conjugates of Schally et al are both functional derivatives of Applicant's Structures I, II, A, B, and C (all are capable of complexing nickel) and structural derivatives of Applicants' Structures I, II, A, B, and C (all comprise phenyl groups, amide groups, amine groups, etc.). Note that neither the claims nor the disclosure requires any particular degree of similarity between a derivative and Applicants' Structures I, II, A, B, and C. Sufficient evidence of similarity is deemed to be present between the conjugates of Schally et al and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than the conjugates of Schally et al.

8. Claims 1-3, 5, 11, 12, 21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Mauclaire et al (U.S. Patent No. 5,268,371). Mauclaire et al teach compound (IV) which has Applicants' structure II. The compound can complex nickel and can be conjugated to an antigen, an antibody, or a hapten. See, e.g., column 5, lines 1-27, and column 8, lines 51-53 and 64-68. The antigens, antibodies, and haptens of Mauclaire et al correspond to Applicants' detectable labels. The conjugates of Mauclaire et al are both functional derivatives of Applicants' Structures I, II, A, B, and C (all are capable of complexing nickel) and structural derivatives of Applicant's Structures I, II, A, B, and C (all comprise phenyl groups, amine groups, pyridyl groups, etc.). Note that neither the claims nor the disclosure requires any particular degree of similarity between a derivative and Applicants' Structures I, II, A, B, and C. Sufficient evidence of similarity is deemed to be present between the compound of Mauclaire et al and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than the compound of Mauclaire et al.

Art Unit: 1654

9. Claims 1-3, 5, 6, 11, 12, 21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Burrows et al (U.S. Patent No. 5,272,056). Burrows et al teach compounds 9 and 12 which have Applicants' structures I, II, A, and C. The compounds can complex nickel, and can be conjugated to proteins or protein fragments. See, e.g., column 5, lines 60-67; column 6, lines 27-46; column 10, lines 34-39; and column 11, lines 4-39. The proteins and protein fragments of Burrows et al correspond to Applicants' detectable labels. The conjugates of Burrows et al are both functional derivatives of Applicants' Structures I, II, A, B, and C (all are capable of complexing nickel) and structural derivatives of Applicants' Structures I, II, A, B, and C (all comprise phenyl groups, amine groups, pyridyl groups, etc.). Note that neither the claims nor the disclosure requires any particular degree of similarity between a derivative and Applicants' Structures I, II, A, B, and C. Sufficient evidence of similarity is deemed to be present between the compounds of Burrows et al and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than the conjugates of Burrows et al.

10. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by the Woodson et al article (Nucleic Acid Research, Vol. 21, pages 5524-5525). The Woodson et al teaches an Ni-TMAPES complex having the same structure as is recited in the formula of the instant claim. With respect to the claim limitation "labeled", see the above rejection under 35 U.S.C. 112, second paragraph.

11. Claims 1-4 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 97/10854. The WO Patent Application '854 teaches compounds comprising a chelating group labeled with biotin, in which the metal to be complexed can be nickel. See,

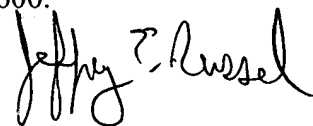
Art Unit: 1654

e.g., the Abstract and claims 1 and 4. The compounds of the WO Patent Application '854 are both functional derivatives of Applicant's Structures I, II, A, B, and C (all are capable of complexing nickel) and structural derivatives of Applicants' Structures I, II, A, B, and C (all comprise phenyl groups, amide groups, amine groups, etc.). Note that neither the claims nor the disclosure requires any particular degree of similarity between a derivative and Applicants' Structures I, II, A, B, and C. Sufficient evidence of similarity is deemed to be present between the compounds of the WO Patent Application '854 and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than the compounds of the WO Patent Application '854.

12. Theodore et al (U.S. Patent No. 6,015,897) is cited as art of interest, teaching biotinylated porphyrin compounds. See, e.g., column 51, lines 15-39. However, Theodore et al do not teach or suggest complexing nickel with these compounds, and there is no motivation to combine Theodore et al with references which do teach nickel-porphyrin complexes.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
September 26, 2006